REMARKS

Claims 1-6, 10-34, and 95 are pending. Claim 1 has been amended. Claims 7-9 and 75-94 were previously canceled without prejudice or disclaimer. Claims 35-74 were previously withdrawn. New claim 95 has been added. No new matter has been introduced. Reexamination and reconsideration of the present application are respectfully requested.

In the December 2, 2008 Office Action, the Examiner rejected claims 1-6 and 10-34 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent App. Pub. No. 2003/0060765 to Campbell et al. (the Campbell reference), in view of U.S. Patent No. 6,544,212 to Galley et al. (the Galley reference). The Examiner rejected claims 1-6 and 10-34 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent App. Pub. No. 2003/0114836 to Estes et al. (the Estes reference), in view of the Galley reference. These rejections are respectfully traversed.

The present invention generally relates to apparatuses and methods for providing blood glucose measurements to an infusion device. Independent claim 1 has been amended to more accurately define the present invention.

Independent claim 1, as amended, recites:

a characteristic determining device including:

a determining device housing adapted to be carried by the user;

a receptacle coupled to the determining device housing for receiving and testing an analyte from the user to determine a concentration of the analyte in the user;

a determining device processor contained in the determining device housing and coupled to the receptacle for processing the determined concentration of the analyte from the receptacle; and

a determining device communication system contained in the determining device housing and coupled to the determining device processor for transmitting a communication including data indicative of the determined concentration of the analyte in the user; and

an infusion device including:

an infusion device housing adapted to be carried by the user;

a drive mechanism contained in the infusion device housing and operatively coupled with a reservoir containing the fluid for infusing the fluid into the body of the user;

an infusion device communication system contained in the infusion device housing for receiving the communication including the data indicative of the determined concentration of the analyte in the user from the determining device communication system;

an infusion device processor contained in the infusion device housing and coupled to the infusion device communication system for processing the data indicative of the determined concentration of the analyte in the user and controlling the infusion device;

a bolus estimator used in conjunction with the infusion device processor for calculating an estimated amount of fluid to be infused into the body of the user based upon the received data indicative of the determined concentration of the analyte in the user and a target concentration of the analyte in the user; and

an infusion device indicator to indicate when the estimated amount of fluid to be infused has been calculated;

wherein the *infusion device processor determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time*.

The Campbell reference is generally directed to a medication infusion device that includes a menu structure that is used to control the infusion device. Independent claim 1, as amended, patently improves upon the Campbell reference by reciting an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon*

the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time.

The Galley reference does not disclose or teach the infusion system of independent claim 1, as amended. The Galley reference is generally directed to an automated system for determining the timing and amount of insulin administration to a subject in the treatment of diabetes. Unlike independent claim 1, as amended, the Galley reference does not make any mention of an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time*. The Galley reference only shows that a feedback algorithm may be used in connection with basal rate control, and a feedforward algorithm may be used in connection with compensation control for meals and/or exercise (see col. 6, lines 57-66). The Galley reference is entirely silent as to making a determination as to the age of the data to be used in calculating a fluid dosage (e.g., insulin dosage), and preventing such calculation if it is determined that the age of the data to be used in the calculation is too old and has expired, as claimed in independent claim 1, as amended.

In fact, the Galley reference actually teaches away from the infusion system of independent claim 1, as amended, in that if a current/recent glucose level value is

unavailable, the Galley reference will actually make a prediction as to the current glucose level value and determine an insulin dosage recommendation based on this prediction (see col. 5, lines 54-65). In contrast, the infusion system of independent claim 1, as amended, will prevent the calculation of a dosage if the age of the data used to calculate the dosage is too old, because predictions do not always accurately reflect the actual true value, and the concentration of analyte in the body can vary significantly over time for many users. An improper dosage determined using inaccurately predicted data actually may cause greater harm. The infusion system of independent claim 1, as amended, which *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time*, is capable of providing safer and more accurate therapy based on current data than using predictions of old and expired data that may potentially lead to harmful consequences. Accordingly, applicants respectfully submit that independent claim 1, as amended, distinguishes over the Galley reference.

The Estes reference is generally directed to methods and systems for the infusion of insulin. Independent claim 1, as amended, patently improves upon the Estes reference by reciting an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data*

indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time. Accordingly, applicants respectfully submit that independent claim 1, as amended, distinguishes over the above-cited references.

Claims 2-6, 10-34, and 95 all depend, directly or indirectly, from independent claim 1, as amended. Accordingly, applicants respectfully submit that claims 2-6, 10-34, and 95 distinguish over the above-cited references for the reasons set forth above with respect to independent claim 1, as amended.

Applicants believe that the foregoing amendments place the application in condition for allowance, and a favorable action is respectfully requested. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at (818) 576-5291 to discuss the steps necessary for placing the application in condition for allowance should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

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By: /Eric S. Chen/
Eric S. Chen
Reg. No.: 43,542
Attorney for Applicants

MEDTRONIC MINIMED, INC.
18000 Devonshire Street
Northridge, CA 91325-1219
Telephone: (818) 576-5291
Facsimile: (818) 576-6202